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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,580	07/27/2001	Shinya Uchida	0397-0431P	8191

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EXAMINER

COOK, LISA V

ART UNIT PAPER NUMBER

1641

DATE MAILED: 09/06/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/915,580

Applicant(s)

UCHIDA ET AL.

Examiner

Lisa V. Cook

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 27 July 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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### **DETAILED ACTION**

1. Please note that the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all correspondence regarding this application should be directed to Group Art Unit **1641**. All communications should be directed to **Lisa V. Cook**, whose telephone number is **(703) 305-0808**.

2. Currently, claims 1-10 are pending and under consideration.

#### ***Priority***

3. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file. Application No. 2000-226270 filed in JAPAN 7/27/00.

Should applicant desire to obtain the benefit of foreign priority under 35 U.S.C. 119(a)-(d) prior to declaration of an interference, a translation of the foreign application should be submitted under 37 CFR 1.55 in reply to this action.

#### ***Information Disclosure Statement***

4. The listing of references in the specification is not a proper information disclosure statement. For example see page 12. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner-on form PTO-892 or the applicant-on form PTO-1449 have cited the references they have not been considered.

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5. The information disclosure statement (IDS) filed 7/27/01 in paper #2 has been considered as to the merits before First Action. The information disclosure statement filed 7/27/01 in paper #2 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. Only the English abstract of document number A1 048214 filed 2/20/98 in Japan was considered. Document number B22 912413 filed 4/9/99 in Japan has not been considered because an English translation was not filed. It has been placed in the application file, but the information referred to therein has not been considered.

#### *Drawings*

6. No drawings were filed in the instant application.

#### *Specification*

7. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

I The use of the trademarks has been noted in this application. (i.e. Sysmex on pages 8 and 12). They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

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II The incorporation of essential material in the specification by reference to a foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference. The amendment must be accompanied by an affidavit or declaration executed by the applicant, or a practitioner representing the applicant, stating that the amendatory material consists of the same material incorporated by reference in the referencing application. See *In re Hawkins*, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); *In re Hawkins*, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); and *In re Hawkins*, 486 F.2d 577, 179 USPQ 167 (CCPA 1973). Specifically the disclosure of Application No. 2000-226270 is incorporated in its entirety.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-10 (specifically claims 1 and 5) are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 1 is vague and confusing because the last step in the body of the claim is not consistent with the preamble of the claim. Also it is not clear as to what is being agglutinated, the erythrocytes? Please clarify.

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B. Claim 5 is vague and indefinite because it is unclear in reciting "a principle of flow cytometry" because it is not clearly understood what this limitation entails. Is it applicant intent to claim a flow cytometry apparatus or some other parameter found in a flow cytometry apparatus? As recited, one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Appropriate correction required.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Yamao et al. (US Patent #6,030,845).

Yamao et al. disclose an immunoassay method for lysed whole blood. Antibodies in the sample (whole blood) are subjected to agglutination reaction with insoluble carriers or an insoluble particle suspension reagent on to which the antibodies or antigens are immobilized. The agglutination mixture may be lysed with a low osmotic solution, a solution of saponins, freeze/thawing, or by ultrasonication. The resulting agglutination reaction mixture is analyzed for the change in absorbance or in its light scatter by irradiation. See abstract and column 2, lines 9-67.

***Claim Rejections - 35 USC § 103***

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negative by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

II. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamao et al (U.S. Patent #6,030,845) in view of Bester et al. (Analytical Biochemistry, Vol. 223, No.2, pages 299-305, 1994).

Please see Yamao et al. as set forth above.

Yamao et al. differ from the instant invention in not specifically teaching the utility of an erythrocyte-lysing agent (such as sodium dodecyl sulfate) to lyse erythrocytes.

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However Bester et al. teach methods of employing and optimizing lysing agents like sodium dodecyl sulfate (SDS). See abstract. Bester et al. further disclose that the use of SDS with fluorescent dyes could be optimized to quantify DNA in cell cultures. See page 299 2<sup>nd</sup> column 1<sup>st</sup> paragraph.

It would have been obvious to one of ordinary skill in the art at the time of the invention to employ SDS as a lysing agent to lyse cells as taught by Bester et al. in the method of Yamao et al. because Bester et al. taught that SDS was effective in cell dissolution. See page 299, 2<sup>nd</sup> column, 1<sup>st</sup> paragraph. One of ordinary skill in the art at the time the invention was made would have been motivated to incorporate the SDS in cellular analysis to therein take advantage of its known dissociation properties.

III. Claims 4-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yamao et al. (U.S. Patent #6,030,845) in view of Kosako (U.S. Patent #5,527,714) and Cohen et al. (U.S. Patent #4,851,329).

Please see Yamao et al. as set forth above.

Yamao et al. fail to particularly teach flow cytometry analysis, particle size, and particle to sample ratios.

However, Kosako disclose a method for determining particle size distributions with respect to an analyte via mediated particle agglutination. The method involves the utility of antigen/antibody reactions to concentrated sensitized insoluble carriers into non-aggregated and aggregated particles of known size.



The analyte is analyzed by an electronic analyzer to detect the quantity and size distribution of concentrated non-aggregated and aggregated insoluble carriers resulting from the antigen/antibody reaction, as well as spurious particles that may be present in the analyte. See column 1 line 65 through column 2 line 9. The calculation with respect to T and M as recited in claim 6 is taught by Kosako (5,527,714) column 4 lines 36-50.

Cohen et al. also disclose a method of determining the concentration of antibody and antigen molecules with high specificity, accuracy, and sensitivity. The process can be used to determine concentration of any substance capable of promoting or inhibiting an agglutination reaction. See abstract. The process is based on the relationship between cluster size of aggregated particles and the intensity of light scatter from the particles as they traverse a beam of focused light. Column 2 lines 62-67. The particle size range from 0.03 up to about 5-10 microns. Column 4, lines 24-26. In the example in column 7 the mixture of particle to sample was taught to be 1:11 (see column 7 lines 54-55).

It would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate the flow analysis teachings of Kosako and Cohen et al. into the method of Yamao et al. because Kosako taught that his method detected small percentages of an analyte with improved sensitivity and decreased sample preparation time. Column 1 lines 30-34. The agglutination process further allowed for spurious particle elimination Column 2 lines 10-16. While, Cohen et al. taught that his method resulted in high intrinsic sensitivity and specificity of the agglutination reaction, improved light scatter detection, while identifying contaminants. Column 6 line 57 through column 7 line 25.

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One of ordinary skill in the art at the time the invention was made would have been motivated to measure agglutination in flow cytometry particle analyses to more accurately measure the analyte with various particle parameters thus allowing for increased data sets for consideration and evaluation.

IV. Claims 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yamao et al. (U.S. Patent #6,030,845) in view of Holmes (U.S. Patent #4,830,969).

Please see Yamao et al. as set forth above.

Yamao et al. differ from the instant invention in not teaching the immune agglutination reaction temperature and time recited in claim 10.

However Holmes disclose a process for the separation of cellular materials. The cellular material is heated in a solution of lysing agent (including surfactants) to agglomerate water-soluble nitrogen containing compounds. See abstract. In general the temperature is between about 60° and about 105°C., preferably between 80° and 105°C. The time is between about 10 seconds and about 3 minutes. Column 2, lines 54-63. Therein reading on the limitations of claim 10.

It would have been obvious to one of ordinary skill in the art at the time of the invention to utilize the temperature and time ranges taught by Holmes in the method of Yamao et al. because Holmes taught that this process (temp and time) allowed one to separate agglomeration resistant water soluble nitrogen containing cellular organic compounds like nucleic acids and peptides from other cellular materials. Column 2, lines 1-9.

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Further the need for isolating plasmids and other nucleic acids has become critical due to the extremely rapid growth of microbiological analysis and genetic engineering. Column 1, lines 56-65.

One of ordinary skill in the art at the time the invention was made would have been motivated to utilize the process taught by Holmes because it was rapid, simple, and inexpensive. Column 1 lines 51-55.

11. For reasons aforementioned, no claims are allowed.

***Remarks***

12. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Lehnen (U.S. Patent #5,567,627) teach methods and reagents useful in the simultaneous and discrete analysis of multiple analytes.

B. Terstappen et al. (U.S. Patent #5,646,001) affinity-binding separation and release of one or more selected subset of biological entities from a mixed population thereof.

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13. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 308-4242, which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (703) 305-0808. The examiner can normally be reached on Monday-Friday from 8:00 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Lisa V. Cook

CM1-7B17

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8/26/02



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